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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,666	11/28/2000	Roman Sakowicz	UCSD-04873	9298

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	5

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,666	SAKOWICZ ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The preliminary amendment filed November 28, 2000 has been entered. Claims 1-57 have been cancelled. Claim 58 is under consideration in this office action.

Priority

2. The status of nonprovisional parent application(s) for which applicant desires priority (whether patented or abandoned) should be updated. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Oath/Declaration

3. An inconsistency in the declaration was noticed, the declaration refers to application 60/072,361 with a filing date of January 23, 1999 instead of January 23, 1998, however the first line of the specification is correct; therefore no action is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 58 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of identifying agents that bind to TL-γ of SEQ ID NO:1 and 2 or identified portions, does not reasonably provide enablement for agents which bind to TL-γ or portions thereof which encompasses any and all biologically functional equivalents and sequences unknown to the inventor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches that novel nucleotide sequences that encode TL-γ or fragments as identified in SEQ ID NO:1 or 2. See the specification from page 25 that describes the nucleotide sequences encoding TL-γ and related nucleic acid sequence homologues cloned and isolated from *Thermomyces languinosus*. There are no examples within the specification of any other sequences that the candidate agents can bind to. The specification fails to teach examples of any and all biologically functional equivalents or currently unknown sequences. The specification appears to make the conclusion that any TL-γ or portions thereof can be used in the method of identification without any substantiating evidence. Therefore, the claims are only enabled for the use of known TL-γ sequences.

Applicants claims are not limited to nucleic and amino acids which encode solely the TL-γ protein but rather include language such as biological functional equivalents, inter- and intra-species homologues and alleles which broadens the claims such that the claims encompass any recombinant DNA, vector, or cell which encodes any protein

having sufficient TL-γ biological activity such that it may properly be considered a biologically functional equivalent of the protein having the nucleic acid of SEQ ID NO:1; as defined by the instant specification at page 9 lines 1-25. See *Ex parte Maizel*, 27 USPQ2d 1662. Applicants have provided no guidance as to the nature and extent of the procedures that must be encompassed to enable one of ordinary skill in the art as to how to make, without undue experimentation, to use a method of identifying agents that bind to the broadly claimed TL-γ. Given the lack of guidance contained in the specification and the unpredictability for using a method of identification of agents which bind to the broadly identified TL-γ, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Furthermore, the specification fails to provide an enabling disclosure for the use of any form of the TL-γ or portions thereof in a method of identification as recited in the claims. Applicants' have provided no guidance to enable one of ordinary skill in the art as to how determine, without undue experimentation, other TL-γ or portions thereof. There is no requirement for the use of only the use of only known sequences of TL-γ. Given the lack of guidance contained in the specification and the unpredictability for determining an acceptable TL-γ, one skilled in the art could not make or use the broadly claimed invention without undue experimentation.

5. Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO:1, 2 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claim drawn to broadly interpreted meanings of TL-γ protein which includes inter- and intra-species homologues, alleles, orthologs, biological functional equivalents, or cells which encodes any protein having sufficient TL-γ biological activity such that it may properly be considered a biologically functional equivalent of the protein.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of allelic sequences, inter- and intra-species homologues, biological functional equivalents, or cells which encodes any protein having sufficient TL-γ biological activity such that it may properly be considered a biologically functional

equivalent of the protein are not defined. With the exception of SEQ ID NO:1 and 2, the skilled artisan cannot envision the detailed structure of the encompassed TL-γ and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

However, no disclosure, beyond the mere mention of inter- and intra-species homologues, alleles, orthologs, biological functional equivalents, is made in the specification. This is insufficient to support the generic claims as provided by the

Interim Written Description Guildlines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an isolated DNA molecule comprising a DNA sequence consisting of SEQ ID NO:1, 2 and equivalent degenerative codon sequences thereof, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

6. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Acronyms like TL-γ must be spelled out when used for the first time in a chain of claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 58 is rejected under 35 U.S.C. 102(a) as being anticipated by Alphey et al. Alphey et al., identified another member of the kinesin superfamily,which are microtubule-based mechanochemical motors (page 395). Kinesin-related proteins have been found in a wide variety of organisms, including several fungi (page 395). Kinesins

and kinesin-related proteins may share a conserved motor domain that defines the superfamily (page 395). The materials and methods section teach an in vitro binding assay (page 397). Protein phosphatase (PP) was used in the binding assay, since PP1 is known to stimulate kinesin motor activity (page 396). The in vitro binding assay used a labeled kinesin protein ^{35}S-labeled Kinesin Like Protein, (KLP38B) and oligo-histidine-tagged PP1 beads (page 397). Figure 2 shows sequence alignments with unc104-related kinesin-related proteins that share similarity outside the motor domain and conserved regions shared between all kinesin-related proteins. Figure 9 demonstrates the in vitro binding. Thus, the authors identified novel kinesin-related proteins in a screen for PP1-binding proteins and demonstrated the physical association between kinesin-related protein and protein phosphastases (page 407).

Therefore, the method of Alphey et al., identifies agents, such as PP1, and binding regions that binds to equivalent portions of TL-γ in view of conserved homology between members of the kinesin and kinesin-like superfamily proteins and inherently include TL-γ portions.

8. Claim 58 is rejected under 35 U.S.C. 102(b) as being anticipated by Nangaku et al. Nangaku et al., teach KIF1B, a novel member of the mouse kinesin superfamily, which is a microtubule plus end-directed monomeric motor protein for transport of mitochondria. The KIF1B is related to other members of the kinesin superfamily, and is the mouse counterpart to *Caenorhabditis elegans* UNC-104 which it shares high sequence similarity too (page 1209). Comparisons of partial sequence similarity can be

seen in Figure 1C. The authors perform in vitro motility assays, such as a microtubule gliding assays wherein the addition of casein, prevented the microtubule-translocating ability of KIF1B (page 1213). Another experiment showed that when anti-KIF1B antibody was added to the solution containing the KIF1B peptide, the number of mitochondria attached to the microtubules decreased significantly; see Table 2 which shows antibody inhibition assay of KIF1B motility in vitro. Thus the antibodies are candidate agents which bind portions of TL-γ portions which appear to be equivalent to the kinesin superfamily proteins, KIF1B.

In view of applicants admission that novel members of kinesin superfamily such as the unc-104 family and KIF1B (see specification page 2) are significantly related to TL-γ, it would appear that the identification of agents which bind to KIF1B will inherently bind to portions of TL-γ also. Therefore, Nangaku et al., teach a method for identifying agents which bind to TL-γ or portions thereof; comprising adding a candidate agent, such as an antibody, and identifying whether the agent binds.

Prior Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blangy et al., teach protein kinases regulate binding of kinesin-related motor proteins. Goldstein et al., teach kinesin family members. Sekine et al., teach a novel microtubule-based motor protein KIF4 for organelle transports.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na A Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines JH
March 21, 2002

PATRICIA A. DUFFY
PRIMARY EXAMINER